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May 6, 2005

VIA UPS OVERNIGHT DELIVERY

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

RE: Ribavirin, USP Tablets, 500 mg

SUITABILITY PETITION

The undersigned submits this Suitability Petition in quadruplicate pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(C), and FDA regulations, 21 C.F.R. §§ 314.93, 10.20, 10.25 and 10.30.

A. Action Requested

This Suitability Petition requests a declaration by the Commissioner of Food and Drugs, head of the Food and Drug Administration ("FDA"), permitting the submission of an Abbreviated New Drug Application ("ANDA") for ribavirin, USP tablets in a strength of 500 mg.

B. Statement of Grounds

An ANDA may be submitted for the approval of a new drug that has the same active ingredient as a reference listed drug ("RLD"). 21 U.S.C. § 355(j)(2)(A)(ii)(I). An ANDA may also be submitted for a drug product whose strength differs from that of the RLD, upon approval by the FDA of a suitability petition for such a change. 21 U.S.C. § 355(j)(2)(C).

The specific RLD upon which this Suitability Petition is based is COPEGUS™ (ribavirin, USP) tablets, 200 mg (NDA 21-511 held by Roche Laboratories, Inc.), a drug which is indicated in combination with peginterferon alfa-2a for the treatment of adults with chronic hepatitis C virus infection who have compensated liver disease and who have not

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been previously treated with interferon alpha. (See COPEGUS™ package insert and medication guide, Attachment 1 hereto).

The proposed drug products will contain the same active ingredient as the RLD COPEGUS™, the same dosage form (tablet), and the same route of administration (oral). The proposed drug products will differ from the RLD only in the strength offered. The RLD strength is 200 mg. The strength of the proposed drug product will be 500 mg.

The dosage strength of ribavirin in the proposed drug product, 500 mg, for the proposed dosage regiment, twice daily, falls within the dosage range specified in the labeling of the RLD COPEGUS™. The labeled dose recommendations for the RLD are 800 mg to 1200 mg administered orally in two divided daily doses, which are individualized to the patient depending upon baseline disease characteristics (such as genotype), response to therapy and tolerability of the regimen (see Attachment 1, p. 20, second paragraph, and Table 4).

The proposed dosage strength of ribavirin, 500 mg, will enable patients who weigh less than 75 kilograms the convenience of taking a single ribavirin tablet twice daily to achieve the 1000 mg labeled dosage, rather than having to take either two of the presently available tablets during a first administration daily and three of the presently available tablets during a second administration daily or three of the presently available tablets during a first administration daily and two of the presently available tablets during a second administration daily to achieve the 1000 mg labeled dosage, as is the case with the existing 200 mg ribavirin tablet. The proposed 500 mg ribavirin tablet will be administered as one tablet during the first administration and one tablet during the second administration on a daily basis. The proposed 500 mg ribavirin tablet will result in a decreased number of units of product the patient will have to take per administration per day, thereby making it easier for patients to comply with their prescribed dosing schedule. In published studies, therapeutic compliance is cited as an important role in the overall success of treatment and improvement of outcomes.

The labeling of the proposed drug product will be the same as the currently approved labeling for the RLD, except for changes which are required because of the difference of manufacturer and the difference in strength as proposed under this Suitability Petition. (See proposed package insert and medication guide for the proposed 500 mg strength of ribavirin, in Attachment 2 hereto).

In view of the above, and because ribavirin, USP in combination with peginterferon alpha-2a has been marketed in the United States for almost two years with an established safety and efficacy profile (see Attachment 1), there is no reason to question the safety and effectiveness of the proposed ribavirin drug product.

C. Environmental Impact

The Petitioner claims a categorical exclusion from the requirement of an environmental assessment of environmental impact statement pursuant to 21 C.F.R. § 25.31.

D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of this Suitability Petition.

E. Pediatric Assessment

A change in dosage strength does not require a pediatric assessment under the Pediatric Research Equity Act. (See 21 U.S.C. § 355b(a)(1)(A)).

F. Certification

The undersigned certifies that, to their best knowledge and belief, this Suitability Petition includes all information and views upon which the Petition relies, and includes representative data and information known to Petitioner which are unfavorable to the Petition.

Respectfully submitted,

Kilpatrick Stockton, LLP

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Attachments